# Obstetrician and Gynaecologist, Dr B Private Clinic

# A Report by the Deputy Health and Disability Commissioner

(Case 19HDC01255)



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# **Executive summary**

- 1. This report highlights the importance of the informed consent process and, in particular, of providing consumers with all relevant information to allow them to make an informed decision on their care.
- A woman in her forties underwent surgery in 2013 for the management of a pelvic mass. The surgery included a bilateral oophorectomy (the surgical removal of both her ovaries), performed at a private clinic by an obstetrician and gynaecologist. This report considers the adequacy of the information provided to the woman in relation to the bilateral oophorectomy to allow her to provide informed consent to the procedure.

#### **Findings**

- The Deputy Commissioner had concerns about the adequacy and appropriateness of the informed consent discussions undertaken by the obstetrician and gynaecologist specifically, the information that was provided to the woman prior to her signing the consent form, including the lack of discussion about the options available, and the clinical rationale for, and risks/side effects associated with, ovary removal. The Deputy Commissioner found the obstetrician and gynaecologist in breach of Right 6(1) of the Code. The Deputy Commissioner also considered that due to the obstetrician and gynaecologist's omissions, the woman was not in a position to make an informed choice about the proposed surgery. Accordingly, the Deputy Commissioner found the obstetrician and gynaecologist in breach of Right 7(1) of the Code.
- 4. The private clinic was not found in breach of the Code.

#### Recommendations

5. It was recommended that Dr B provide a written apology.

# **Complaint and investigation**

- 6. The Health and Disability Commissioner (HDC) received a complaint from Ms A about the services provided by obstetrician and gynaecologist Dr B. The following issues were identified for investigation:
  - Whether Dr B provided Ms A with an appropriate standard of care in 2013.
  - Whether the clinic provided Ms A with an appropriate standard of care in 2013.
- 7. This report is the opinion of Rose Wall, and is made in accordance with the power delegated to her by the Commissioner.

8. The parties directly involved in the investigation were:

Ms A Consumer/complainant

Dr B Provider/obstetrician and gynaecologist

Private clinic Provider

- 9. Further information was received from Ms A's general practitioner (GP), the private hospital where the events took place, and the district health board.
- 10. Reference is also made to obstetrician and gynaecologist Dr C, who provided independent advice to ACC.
- 11. Independent advice was obtained from obstetrician and gynaecologist Dr Ian Page (Appendix A).

# Information gathered during investigation

Ms A, aged in her forties at the time of events, underwent surgery for the management of a pelvic mass. The surgery included a bilateral oophorectomy (the surgical removal of both her ovaries). This report concerns the care provided by obstetrician and gynaecologist Dr B, in particular his decision to undertake a bilateral oophorectomy in the circumstances, as well as the information he provided to Ms A prior to obtaining her consent.

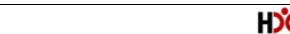
#### Dr B

Dr B has held vocational registration with the Medical Council of New Zealand in obstetrics and gynaecology for many years. At the time of these events, Dr B was a Fellow of the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG), and a director of the clinic. Dr B told HDC that he had extensive experience in gynaecological and oncology surgery.

#### **Background**

On 22 March 2013, Ms A underwent a laparoscopy<sup>2</sup> at a public hospital to remove her gallbladder.<sup>3</sup> The surgery was complicated by an injury to the abdominal aorta,<sup>4</sup> which

<sup>&</sup>lt;sup>4</sup> The largest artery in the abdominal cavity.



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<sup>&</sup>lt;sup>1</sup> The clinic is an umbrella company of which Dr B was a director. The clinic told HDC: "[The clinic] is a cost sharing company only and all the specialists who work here have their own contracts with insurance providers, who pay them directly ... the clinic is not involved in any clinical decision making or patient care, as was the case when [Dr B] provided his medical services to [Ms A], and this responsibility rests with the individual specialist."

<sup>&</sup>lt;sup>2</sup> Keyhole surgery — a type of surgery in which the surgeon uses only small cuts (incisions) to get through the skin.

<sup>&</sup>lt;sup>3</sup> A laparoscopic cholecystectomy.

necessitated a conversion to an open incision. Postoperatively Ms A experienced a number of complications.

- On 11 April 2013, Ms A developed shortness of breath and right-sided chest pain, and was admitted to the public hospital for investigation of a possible blood clot in an artery in the lung. The pain resolved and Ms A was discharged. A pelvic CT<sup>7</sup> scan performed at the time showed a large mass in her pelvic region. 8
- 16. On 21 April 2013, Ms A developed left-sided back/leg pain and was diagnosed in the emergency department with a deep vein thrombosis (DVT), which initially was treated with medications to help break down the clot, but eventually required surgical clean-out and the insertion of a stent (a small tube to hold the vein open). Ms A told HDC that a Grade 2 stocking was fitted to her left leg, and blood-thinning medication was initiated, with a subsequent scan (performed later that day) showing that the vein had blocked again. She said that she was informed that nothing more could be done and she would need to remain on blood thinners for 9–12 months. Following her discharge from hospital, Ms A experienced ongoing leg pain and weakness.
- On 31 May 2013, Ms A developed abdominal pain, which was worse on the left than on the right. Ms A was referred for a surgical opinion, and a further CT scan of the abdomen confirmed a large mass measuring 13.3 x 13.6cm in the area between her uterus and rectum. The CT report noted that it was largely unchanged compared to the previous CT scan.<sup>10</sup>
- On 20 August 2013, a repeat CT scan of the abdomen identified a large pelvic mass measuring 15 x 10.7cm, which was displacing the uterus towards the left; however, the mass was unable to be categorised clearly. It was noted that the mass had not changed from previous imaging. An MRI scan left pelvic ultrasound was recommended. At that time, Ms A reported ongoing bladder symptoms, including urinary urgency and occasional incontinence.
- On 3 September 2013, an abdominal ultrasound confirmed the presence of a large mass, but it was unclear whether or not the growth had arisen from the uterus. The ovaries were

<sup>&</sup>lt;sup>5</sup> A laparotomy.

<sup>&</sup>lt;sup>6</sup> A pulmonary embolism.

<sup>&</sup>lt;sup>7</sup> Computed tomography — a type of X-ray that gives cross-sectional images.

<sup>8</sup> Documented as: "Large pelvic collection ?retracting haematoma."

<sup>&</sup>lt;sup>9</sup> A blood clot in a deep vein.

<sup>&</sup>lt;sup>10</sup> The report documented: "Large heterogeneous mass within the pouch of Douglas [a small area between the uterus and rectum] suggestive of retracted haematoma is largely unchanged compared to previous imaging." <sup>11</sup> The CT scan report documented: "A large pelvic mass with some vascularity which is unusual for a haematoma … ? Right adnexal mass/large fibroid is likely." An adnexal mass is an abnormal growth that develops in or near the ovaries, fallopian tubes, or surrounding connective tissues.

<sup>&</sup>lt;sup>12</sup> Magnetic resonance imaging is a type of scan that produces detailed images of the organs and tissues.

both noted to be of normal size and appearance, and separate from the mass. An MRI scan was recommended.<sup>13</sup>

- 20. An MRI scan was performed on 10 September 2013. The scan report confirmed the presence of a large mass that was thought to be a retroperitoneal fibroid, <sup>14</sup> although cancer could not be excluded. <sup>15</sup> A gynaecology review was recommended.
- On 20 September 2013, blood results showed that Ms A had a slightly raised CA125 $^{16}$  of 35.6 U/mL (the normal range of CA125 is 0–21).
- 22. On 23 September 2013, Ms A's GP sent a referral for gynaecology review to a private clinic (the clinic).

# Referral to Dr B and decision for surgery

Dr B first saw Ms A on 25 September 2013. His record of the consultation noted that Ms A's presenting symptoms included bladder pressure/lower abdominal discomfort, a 15 x 10.7cm pelvic mass, and left foot drop, which had started when the DVT was diagnosed. Dr B noted that on examination, the pelvic mass felt "like [an] ovarian cyst". He documented the following plan:

"Review MRI Tuesday
Hysteroscopy<sup>17</sup> D&C<sup>18</sup>/insert Mirena IUCD<sup>19</sup>
Laparotomy/bilateral oophorectomy/Omental biopsy<sup>20</sup> Tuesday 8/10/13"

24. In his clinic letter to Ms A's GP, dated 25 September 2013, Dr B documented:

"[Ms A] has a large mass in the left pelvis which is undoubtedly ovarian in origin but I will review that MRI with our radiologists before she has surgery. ...

She needs the mass removed. It would be best to remove both ovaries and take an omental biopsy at the same time. The uterus can remain but it would help to insert a Mirena IUCD to reduce her heavy bleeding on anticoagulation<sup>21</sup>."

<sup>&</sup>lt;sup>21</sup> Medication being taken to prevent and/or treat blood clots.



<sup>&</sup>lt;sup>13</sup> The report documented: "Unusual right adnexal/pouch of Douglas mass, separate to both ovaries, but it is not possible to be sure whether this arises from the uterus or not."

<sup>&</sup>lt;sup>14</sup> Also known as a leiomyoma — a type of tumour that is usually benign.

<sup>&</sup>lt;sup>15</sup> The scan report documented: "Appearances are compatible with a large pedunculated right uterine/broad ligament leiomyoma, with features of myxoid degeneration. This produces a complex appearance and it is not possible to exclude malignant transformation, but there is no evidence of overt malignancy." A broad ligament leiomyoma is a tumour that is attached to the uterine wall. Myxoid degeneration is a process where the fibroid/leiomyoma is filled with a gelatinous material.

<sup>&</sup>lt;sup>16</sup> A type of tumour marker test that can be elevated in the presence of cancer.

<sup>&</sup>lt;sup>17</sup> An examination of the inside of the cervix and uterus.

 $<sup>^{18}</sup>$  Dilation and curettage — a procedure to remove tissue from inside the uterus.

<sup>&</sup>lt;sup>19</sup> A hormonal intrauterine device that is used for contraception or to reduce heavy menstrual bleeding.

<sup>&</sup>lt;sup>20</sup> A sample of cells taken from the omentum (tissue that lines the abdomen) to check for the presence of abnormal cells.

In relation to his recommendation that a Mirena IUCD be inserted, Dr B said that this was appropriate given that Ms A was experiencing heavier bleeding on long-term anticoagulants. He noted that this was particularly relevant since Ms A was a candidate for hormone replacement therapy.

#### Rationale for ovary removal

26. Dr B told HDC that the "prime drivers" for undertaking the bilateral oophorectomy were the potential involvement of the ovarian blood supply in the mass, and the potential that the mass was oestrogen dependent. He stated:

"[T]he right ovary was removed due to it sharing a blood supply with the tumor, and the histological sample required (wide margins, ideally clear of microscopic malignant deposits)."

- 27. Dr B said that the left ovary was removed to prevent oestrogen production, which could contribute to the development of disease (if present), and "removing the supply of oestrogen is important for ongoing management and prevention of recurrence of any oestrogen dependent tumour, benign or malignant".
- 28. In relation to the risk of re-operation had the mass been malignant, Dr B told HDC:

"Pelvic and abdominal laparotomy carries a high risk of thromboembolic disease and haemorrhage. Dissection of major adhesions from previous bowel perforation carry a high risk of further bowel injury. Deep dissection of the pelvic sidewall carries a risk of ureteric and vascular injury. Any of these could be lethal so it would be very unwise to leave a surgical situation that risks another operation."

- 29. Dr B also provided detail of other factors that influenced his decision to recommend a bilateral oophorectomy for Ms A:
  - The indication in the referral of a "large pelvic adnexal mass, variously diagnosed with imaging, that did not present as 'typical' non-cancerous fibroid".
  - The location of the mass, particularly that tumours in the retroperitoneal area are rare and their complex anatomical location presents a diagnostic risk and an enhanced risk of malignancy.
  - "The radiology interpretations using numerous imaging varied considerably, from hematoma to 'malignancy cannot be excluded'."
  - Imaging is not a definitive diagnostic tool for malignancy.
  - Ms A's age at the time of the events.
- on Dr B said that at the time of the events he discussed Ms A's case with a colleague, and he provided a supporting statement from the colleague. Dr B also asserted that were he still practising, his management would be the same.

#### Rationale for retention of uterus

- Dr B told HDC that although (as discussed above) he considered that the mass shared an intimate blood supply with the right ovary, and that the tumour might be oestrogen dependent, it was his view that "[t]here was no attachment to the uterus and the anatomical site".
- Dr B said that he also took into account that he recalled discussing with Ms A her wish to preserve her uterus if possible.

#### **Consent for surgery**

- The "Request & Consent for Treatment" form, signed by both Dr B and Ms A and dated 25 September 2013, lists the planned procedure as a hysteroscopy, dilation & curettage, laparotomy, bilateral oophorectomy, and a biopsy of the omentum. Initially, the insertion of a Mirena IUCD was listed, but this was crossed out. The form states: "I have explained to [Ms A] the benefits and risks of the above surgery treatment." The details of exactly what was discussed are not documented. However, Dr B advised that he recalls discussing the extent of the surgery with Ms A.
- or B told HDC that it was his usual practice to explain what he considered the surgical plan should be, the reasons for that plan, and any reasonable alternatives. Dr B said that in this case, he did not consider that leaving the mass was a reasonable option, and he expects that he would have explained his "perception of an ovarian mass on physical examination, the lack of consensus in the imaging to date and the prospect from that, of a risk of ovarian-related malignancy". He also said that he expects he would have explained the justification for the plan, being that "ovary removal may be necessary for histological examination and to remove oestrogen production (and associated risk)". He stated:

"The uninvolved ovary would have some chance of containing similar pathology to the left ovary. It was important to perform the appropriate surgery to avoid a second operation if the mass was malignant or hormone dependent."

- Dr B said that this was explained to Ms A, but he acknowledged that there is no record of exactly what was discussed.
- In a statement to ACC, Dr B said that Ms A was informed of the risks of removing her ovaries. He stated: "At the age of [Ms A] I do not know of any particular risk to her long term health." However, he noted that there may be acute menopausal symptoms of hot flushes and mood changes, which can last for several years.
- Dr B told HDC that his practice was to return to the previously completed consent form with the patient on the day of the procedure, and that he would again go through the material points, "and invite questions in case anything had changed". Dr B said that in this case, the consent form was revisited and the plan around the insertion of the IUCD was changed, "in accordance with communication after the 25 September consultation".

In contrast, Ms A told HDC that she received very little information prior to the surgery. She said that Dr B reassured her that "there was a 99% probability" that the mass was benign, but she was led to believe that removal of both her ovaries was the only option available. Ms A told HDC:

"At our consultation [Dr B] informed me that my left ovary was completely 'squashed' by the tumour and that my right one was 'damaged'. Expressed in this manner led me to believe that there was no choice but to have both of my ovaries removed. It was on this basis that I felt compelled to consent to their removal."

Further to this, Ms A said that Dr B told her that there would be no consequences of removing her ovaries, and that she may or may not continue to menstruate. Ms A stated:

"[Dr B] never discussed with me how the removal of both of my ovaries would severely impact my quality of life through the detrimental effects their removal has had on my physical and, therefore, mental health. This began shortly post-surgery and continues until this day. Indeed, I recall asking [Dr B] what the consequences of removal of both of my ovaries would be and his response of 'You may bleed. You may not' had me leaving our consultation with the belief there was nothing consequential for me to be concerned. So the negative impact this surgery has had on my quality of life came as a tremendous shock, particularly soon after surgery."

In relation to the recommendation that she have a Mirena IUCD inserted, Ms A told HDC that she had been advised by the public hospital that the anticoagulants she was on would be short term only. She stated:

"Knowing this, and with the understanding there was a potential for temporary 'slightly' heavier bleeding which would stop upon cessation of my anticoagulant treatment, I explicitly declined the insertion of the Mirena."

41. Ms A also told HDC that she had been advised that due to her DVT, she could not have hormone replacement therapy.

#### Surgery and postoperative review

- Dr B told HDC that he discussed Ms A's case at the Tuesday morning multi-disciplinary team (MDT) meeting, immediately prior to the procedure on 8 October 2013. He said that he "reviewed the imaging with [another doctor] verbally and both perceive[d] a right retroperitoneal pelvic mass, with a probability of sarcoma".
- Dr B undertook the surgery at the private hospital on 8 October 2013. He carried out a hysteroscopy and dilation and curettage, then performed a laparotomy and identified a 15cm retroperitoneal mass and a polyp. Dr B documented in the operation record that the mass "may have vascular attachment to [the] back of [the] cervix" and that the ovaries were "separate from the mass and normal". Dr B then excised the mass and performed a bilateral oophorectomy.

44. As noted above, Dr B told HDC:

"The right ovary was removed due to it sharing a blood supply with the tumor, and the histological sample required (wide margins, ideally clear of microscopic malignant deposits). The left ovary was removed to prevent oestrogen production that may contribute to the development of disease (if present)."

Histology later confirmed no evidence of malignancy. Dr B noted that in a situation such as this, where the mass was subsequently found to be benign, "it is understandable that a person may not fully comprehend the necessity of their surgery. This risk must be balanced against inadequate and potentially dangerous limited initial surgical management in the case of malignancy." Dr B stated:

"I wish to reassure [Ms A] that I acted in her best interests at all times. Her complex surgery was carried out safely and as planned by us both. I was relieved to see that she had a benign diagnosis."

On 16 October 2013, Dr B saw Ms A for routine postoperative follow-up. In a letter to Ms A's GP, dated 16 October 2013, Dr B stated:

"The large mass impacted in her pelvis was a fibroid which had grown from the posterior aspect of the isthmus.<sup>22</sup> Both the ovaries were normal but they have been removed.

Her uterus has been retained but she is now menopausal. ... She does not need any further follow up from me."

#### Ms A's complaint

On reviewing the postoperative report, Ms A noted that both her ovaries had been found to be normal. She is concerned and upset that her ovaries were removed despite them being undamaged. Ms A stated:

"I was misinformed and ill-advised about the gravity of the nature of the surgery that was required. [Dr B's] advice left me without any doubt, indeed convinced me:

- There was a negligible probability that the tumour was malignant.
- My ovaries were so severely damaged that the optimal course of action for my full recovery was to have them removed.
- His was the correct surgery plan."

# Dr C's advice to ACC

In 2017, obstetrician and gynaecologist Dr C provided independent advice to ACC as part of its consideration of a treatment injury claim relating to whether there had been a treatment injury as a result of the surgery carried out on 8 October 2013. Dr C advised that bilateral oophorectomy is not indicated for the treatment of leiomyoma but is "frequently performed

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<sup>&</sup>lt;sup>22</sup> A small area at the back of the uterus.

in women of this age group when the possibility of a malignant mass is suspected". However, Dr C also advised:

"The clinical information available would have strongly suggested that the mass was a leiomyoma, and not an ovarian tumour. Therefore the primary treatment that was indicated was resection of the mass. If the mass was originating from the uterus, then it would also have been reasonable to have carried out a hysterectomy. However, in the absence of histology indicating a malignancy, or any clear indication that the mass was arising from the ovaries, bilateral oophorectomy was not required as primary treatment for this mass.

In my opinion division of adhesions and resection of the retroperitoneal tumour was the appropriate treatment in the circumstances. However, in my opinion, bilateral oophorectomy was not a required treatment for this condition, given the clinical information available at the time."

#### 49. Further to this, Dr C stated:

"[Dr B] may have been trying to save [Ms A] from a further operative procedure, but the benefits of this needed to be weighed up against the risks of bilateral oophorectomy at [Ms A's] age."

50. Dr C advised that "most gynaecologists are reluctant to remove normal ovaries before the age of 55 years without careful discussion regarding the risks and benefits to that particular individual".

#### Responses to first provisional opinion

Responses to the first provisional opinion were received from Ms A, Dr B, and the private hospital. Where appropriate, the responses have been incorporated into the "information gathered" section above. In addition, the following responses were received.

#### Dr B

- Dr B said that he discussed Ms A's case at the Tuesday morning multi-disciplinary team (MDT) meeting, immediately prior to the procedure on 8 October 2013. He stated: "I reviewed the imaging with [another doctor] verbally and both perceived a right retroperitoneal pelvic mass, with a probability of sarcoma."
- In relation to whether or not the ovary removal was clinically indicated, Dr B told HDC that it would be very unwise to leave a surgical situation that risks another operation. He said:

"Enough tissue also needs to be removed to allow accurate histological diagnosis and staging in the case of a malignancy. Removing the supply of oestrogen is important for ongoing management and prevention of recurrence of any oestrogen dependant tumour, benign or malignant."

Clinic

- The clinic confirmed that it had nothing further to add in relation to the findings of the provisional opinion.
- The clinic advised HDC that it will continue to review its procedures and any complaints made about individual doctors.

#### Responses to second provisional opinion

Ms A

- Ms A was given the opportunity to provide her comments in response to the "information gathered" section of the second provisional opinion. Ms A reiterated the effect that these events have had on her physical and mental wellbeing. She stated:
  - "[I] really wasn't 'informed' correctly of the direct and ongoing impact [Dr B's] surgery would have on my entire wellbeing, the condition of my ovaries and the overall impact on my life."

Dr B

Dr B was given the opportunity to respond to the second provisional opinion. He had no further comments to make.

# Opinion: Dr B — breach

#### Introduction

- This report considers whether the care provided to Ms A in relation to the decision to undertake a bilateral oophorectomy was reasonable in the circumstances. It also considers the adequacy of the information provided to Ms A in relation to the bilateral oophorectomy to allow her to provide informed consent to the procedure, and the rationale for the proposed IUCD insertion.
- Overall, I accept that the bilateral oophorectomy may have been clinically indicated in Ms A's circumstances, and that retention of the uterus was open to Dr B. Accordingly, I am not critical of these decisions. However, I am concerned that Ms A was not provided with the information that she could have expected to receive to enable her to make an informed decision on whether or not to consent to the procedure. In making my decision, I have taken into account all the evidence gathered during the course of the investigation, including information from Ms A, the clinical records, statements provided by Dr B, independent advice obtained from obstetrician and gynaecologist Dr Ian Page, and independent advice obtained by ACC. I outline my concerns and the reasons for these in more detail below.

# Information and informed consent

60. Prior to the surgery, Ms A signed a consent form that listed bilateral oophorectomy as part of the proposed procedure, and stated that she was aware of the risks.

- However, I am concerned that Ms A was not provided with information that a reasonable consumer would expect to receive in the circumstances. Whilst I have accepted above that a bilateral oophorectomy may have been clinically indicated, given the possibility of malignancy and the risks associated with incomplete removal of the mass (see discussion below), I am concerned that Ms A was not provided with sufficient information about the need for, and risks associated with, the planned procedure (including other options).
- Dr Page advised that given the information available at the time, there were other options available for the management of the mass. He stated:

"As the scans suggested the mass was arising from the uterus, and not an ovary, Dr B should have discussed the options of:

- simply removing the mass
- performing a total abdominal hysterectomy to remove the mass and the uterus from which it was arising (which would have dealt with the issue of Ms A's periods)
- performing a total abdominal hysterectomy and bilateral salpingo-oophorectomy to remove the mass, stop Ms A having further periods and reduce the risk of her developing ovarian cancer in the future.

All the options should have been discussed — there is no doubt that removing the mass was appropriate, and the issue is what else (if anything) needed to be removed with it."

#### Informed consent — ovary removal and associated side effects

#### Removal of ovaries

- It is clear that the information that Dr B provided to Ms A was focused around his view that the mass was ovarian in nature, with a risk of malignancy that could not be excluded without histology (that is, testing of the material of the mass once removed). In a clinic letter to Ms A's GP dated 25 September 2013, Dr B stated that following his initial assessment of Ms A, the pelvic mass was "undoubtedly ovarian in origin". Ms A also told HDC that she recalls being advised that her ovaries were being compressed by the mass and needed to be removed, and that this was the only option available to her.
- 64. However, Dr B said that it was his usual practice to explain what he considered the surgical plan should be, the reasons for that plan, and that any reasonable alternatives would be discussed. Dr B said that in this case, he did not consider that leaving the mass was a reasonable option, and he expects that he would have explained his "perception of an ovarian mass on physical examination, the lack of consensus in the imaging to date and the prospect from that, of a risk of ovarian-related malignancy". He also said that he expects he would have explained the justification for the plan, being that "ovary removal may be necessary for histological examination and to remove oestrogen production (and associated risk)".
- I also note that the consent form that Ms A signed states that alternatives had been discussed. However, there is no documentation that records the content of any informed

consent discussions of this nature with Ms A. Further, Dr B has not suggested that he discussed the other options available in any detail.

- I note that while there was some variation in the imaging taken prior to the procedure, there was no reporting of ovarian abnormality or involvement with the mass. It is also clear from the variation in the imaging that the origin of the mass was in question and could not be ascertained from the imaging alone.
- I acknowledge that Dr B's view that a bilateral oophorectomy was likely clinically indicated understandably affected the information he gave to Ms A as part of the informed consent process. However, I accept Dr Page's advice that there were other options available to Dr B for the management of the mass.
- Accordingly, I consider that Dr B should have explained the lack of clarity around the origin of the mass and the other options available. Whilst I acknowledge that Dr B has said that he provided Ms A with some information, in my view, considering that Ms A was clearly under the impression that the only option available to her was the removal of her ovaries, Dr B's statements suggest that any discussion he did have was focused on justifying the plan, rather than discussing alternatives. With no documentation of the details of such preoperative discussions, Ms A's recollection, and the statements from Dr B suggesting that discussions focused on ovary removal and not other options, I consider it more likely than not that Dr B did not provide Ms A with appropriate information around the need for ovary removal.

Discussion of risks associated with ovary removal

- Before proceeding with ovary removal, Dr B also needed to inform Ms A of the risks and benefits of the proposed procedure, including the long-term effects of removing her ovaries.
- Ms A told HDC that Dr B advised: "[Y]ou may bleed. You may not." She said that because she was led to believe that there would be no long-term side effects, "the negative impact this surgery has had on [her] quality of life came as a tremendous shock, particularly soon after surgery".
- Dr B told ACC that the only risk to Ms A in removing both her ovaries was early onset menopause (including hot flushes and mood changes), and there were no long-term side effects when removing ovaries from a woman in her forties. He said that this was explained to Ms A. Dr B told HDC that he did not record the intent, alternatives, risks and likely outcomes of the planned treatment that was discussed with Ms A prior to her signing the consent form. However, he said that it was his established practice to move through the consent form and discuss each of the factors indicated, offering the patient the opportunity to ask any questions.
- Dr Page advised that the removal of the ovaries prior to menopause is associated with more severe and prolonged vasomotor symptoms (such as hot flushes and night sweats) than those seen following natural menopause, as well as a reduction in libido and more sexual dysfunction. Dr Page advised that these side effects should have been discussed with Ms A.

- Further, Dr Page advised that there is conflicting evidence regarding other long-term health effects (such as coronary heart disease and osteoporosis), and "decisions should be made following patient consultation on an individualised basis". ACC advisor Dr C advised that "most gynacologists are reluctant to remove normal ovaries before the age of 55 years without careful discussion regarding the risks and benefits to that particular individual".
- I accept Dr Page's advice in this regard, and agree that the above risks should have been discussed with Ms A prior to surgery.
- There are two possible scenarios before me either that Dr B discussed but did not document the risks, or that Dr B did not discuss or document the risks. I acknowledge Dr B's comments that his usual process was to discuss the risks and benefits, and he considers that he would have done so in this case. I also note his statement to ACC that he told Ms A that ongoing symptoms would include menopausal symptoms, including hot flushes and mood swings. However, I also note that the risks and side effects that my independent advisor has identified as warranting discussion are more extensive than what Dr B has stated was his usual practice. Accordingly, with the evidence available, including the lack of documentation of a discussion of risks, Dr Page's advice on the extent of what should have been discussed, Ms A's recollections of such discussions, and Ms A's clear distress that formed the basis of her complaint to this Office, I consider that Dr B did not advise Ms A adequately of the risks of the bilateral oophorectomy prior to her signing the consent form.
- In my opinion, there was a clear requirement to advise Ms A of the potential risks of performing a bilateral oophorectomy in her individual circumstances, even if it was believed that the procedure was indicated and was the only option available for the management of the mass. This should have included information about the potential risks specific to Ms A's age.

# Conclusion

- Overall, I have concerns about the adequacy and appropriateness of the informed consent discussions undertaken by Dr B specifically, the information that was provided to Ms A by Dr B prior to her signing the consent form, including the lack of discussion about the options available, and the clinical rationale for, and risks/side effects associated with, ovary removal. Collectively, I consider that these omissions are concerning.
- Accordingly, for the reasons set out above, I conclude that Dr B failed to provide Ms A with information that a consumer in her particular circumstances would expect to receive, and breached Right 6(1) of the Code of Health and Disability Services Consumers' Rights (the Code). Consequently, Ms A was not in a position to make an informed choice about the proposed surgery, and I find that Dr B breached Right 7(1) of the Code.<sup>23</sup>

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<sup>&</sup>lt;sup>23</sup> Right 7(1) of the Code states: "Services may be provided to a consumer only if that consumer makes an informed choice and gives informed consent."

#### Informed consent to removal of uterus — other comment

Dr B told HDC that he considered that a hysterectomy was unnecessary and against Ms A's wishes. However, he does not suggest that he discussed this in any detail with Ms A. I note that the clinical records also do not contain reference to such a discussion. I also acknowledge that Dr B's preoperative discussions would have been guided by his planned operation, which was the bilateral oophorectomy. However, the documentation does not record any discussion of the possibility that the uterus was implicated in the mass and might also need to be removed, or that the option to remove the uterus was available to Ms A given the ambiguity of the imaging.

In my view, given that there was a possibility that the uterus was implicated in the mass, Dr B should have informed Ms A of the possibility that the uterus might need to be removed if it was confirmed during surgery that the uterus was implicated in the mass. Although I acknowledge that Ms A had expressed that she wished to retain her uterus, given that Dr B's rationale for the bilateral oophorectomy was based on the risk of both malignancy and incomplete removal, he should have also discussed with Ms A that removal of her uterus might be required.

In the absence of documentation on this point, and noting that Dr B recollects that Ms A expressed her wish to retain her uterus, I am unable to make a finding as to whether Dr B adequately discussed with Ms A the possibility of uterus removal. However, I remind Dr B of the requirement to document the specifics of informed consent discussions clearly.

# Decision to undertake bilateral oophorectomy — no breach

In a clinic letter to Ms A's GP dated 25 September 2013, Dr B stated that following his initial assessment of Ms A, the pelvic mass was "undoubtedly ovarian in origin". Dr B planned to review the MRI scan with the radiologist prior to surgery, but there is no evidence that this was done.

In terms of malignancy, in a statement to HDC Dr B said that "[i]maging is not a definitive diagnostic tool for malignancy", and explained that preoperatively, because of the "size complexity and unusual anatomical site" of the mass, he considered that it should be regarded as "potentially malignant". Dr B said that his rationale for performing a bilateral oophorectomy at the time was to ensure that the mass was removed in its entirety, to minimise the risk of malignant growth and further surgery. Dr B also stated that preoperative imaging confirmed that there was no attachment to the uterus, and the anatomical site, blood supply and gross appearance of the tumour was of a proliferative tumour, 24 possibly sarcoma, 25 all of which are oestrogen dependent, thus the removal of the other ovary.

<sup>&</sup>lt;sup>26</sup> A hormone involved in normal sexual and reproductive development in women.



<sup>&</sup>lt;sup>24</sup> A tumour that is growing.

<sup>&</sup>lt;sup>25</sup> A type of cancer.

#### Dr B also explained: 84.

"[T]he right ovary was removed due to it sharing a blood supply with the tumor, and the histological sample required (wide margins, ideally clear of microscopic malignant deposits). The left ovary was removed to prevent oestrogen production that may contribute to the development of disease (if present)."

- Dr B's postoperative letter dated 16 October 2013 (written to Ms A's GP) stated that the 85. mass was a fibroid that had grown from the posterior aspect of the isthmus, which is consistent with the operation note, which stated that there was a retroperitoneal mass in the right pelvis and that it might have vascular attachment to the back of the uterus.
- My independent advisor, Dr Page, advised that the MRI report from 10 September 2013 86. stated that the mass arose from the "right posterolateral myometrium with vascular pedicle at least 3cm diameter at the level of the isthmus" and the ovaries were recorded as being "normal".
- Dr Page accepted Dr B's rationale for the removal of Ms A's ovaries, 27 including the risks 87. associated with re-operation if the mass was malignant, but advised that proceeding under that rationale would also require the removal of the uterus in its entirety. Dr Page advised HDC: "As it is not possible to ascertain the limit of a sarcoma by visualisation alone removal of the uterus to which it was attached should have been undertaken."
- Dr Page said that the risks of incomplete removal (of the mass, if malignant) are particularly 88. important "given the potential difficulties with any further pelvic surgery for [Ms A] which [Dr B] correctly notes as the justification for removing her ovaries".
- I acknowledge that this conflicts with the advice given by Dr C, who stated: 89.

"In my opinion division of adhesions and resection of the retroperitoneal tumour was the appropriate treatment in the circumstances. However, in my opinion, bilateral oophorectomy was not a required treatment for this condition, given the clinical information available at the time."

- Predominantly I have relied on the advice of Dr Page to guide my decision. I am confident 90. that Dr Page had the opportunity to review all of the relevant documentation, and, importantly, Dr B was given the opportunity to provide his comments in response to Dr Page's advice. Dr B's comments were then considered by Dr Page as part of the advice he provided to this Office.
- Guided by Dr Page's advice, I accept Dr B's rationale for undertaking the bilateral 91. oophorectomy procedure in the circumstances, given the perceived risk of malignancy and of re-operation if the mass was not removed in its entirety. I discuss removal of the uterus in more detail below.

<sup>&</sup>lt;sup>27</sup> I note that there was some further exchange of information before this conclusion was reached.



#### Decision to retain uterus — no breach

- Dr B told HDC that part of what formed his decision to undertake a bilateral oophorectomy was the risk of incomplete removal of the mass if malignancy was confirmed. I have accepted Dr B's view in this regard.
- 93. However, Dr Page advised:

"[Dr B's] response talks about a hysterectomy being unnecessary and against the patient's request. However his justification for the removal of the ovaries was, in part, to avoid the need for re-operation. That is a reasonable thought, but in that case I would have planned a hysterectomy based on the radiological report stating the appearances are compatible with a large pedunculated right uterine/broad ligament leiomyoma. It would not be possible at surgery to determine where any malignancy within the mass would end, and as pedunculated means attached to the uterus I believe the proposed surgery should have included a hysterectomy."

- Dr B told HDC that he considered that a hysterectomy was unnecessary and against Ms A's request. He also advised that he considered Ms A's pre- and postoperative risk, and that the uterus does not produce hormones, meaning that its removal alone would not improve the cure of a future or separate peritoneal mass. The operation note also does not indicate that the mass derived from the uterus.
- In my view, removal of the uterus was a judgement call, and either approach was likely open to Dr B. Accordingly, I am not critical of the clinical decision to retain the uterus. However, as discussed below, in my view the option of uterus removal should have been discussed with Ms A more thoroughly.

#### IUCD — adverse comment

I am also concerned about Dr B's recommendation to insert a Mirena IUCD to control Ms A's heavy menstrual periods. In his clinic letter to Ms A's GP, dated 25 September 2013, Dr B documented:

"She needs the mass removed. It would be best to remove both ovaries and take an omental biopsy at the same time. The uterus can remain but it would help to insert a Mirena IUCD to reduce her heavy bleeding on anticoagulation<sup>28</sup>."

- 97. Dr B said that his recommendation of a Mirena IUCD was appropriate for someone such as Ms A, who had heavy bleeding while on long-term anticoagulants and was suitable for hormone replacement therapy.
- However, Ms A told HDC that she had been advised that she was to be on anticoagulants only in the short term, and for this reason she explicitly declined the insertion of a Mirena IUCD. Ms A also said that she had been advised that due to her DVT, she could not have hormone replacement therapy.

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<sup>&</sup>lt;sup>28</sup> Medication being taken to prevent and/or treat blood clots.

- Dr Page advised that Dr B's planned operation, which included a bilateral oophorectomy, meant that Ms A's menstrual periods would cease. Dr Page considers that the insertion a Mirena IUCD would therefore be "completely illogical, and a severe departure from an accepted standard of care".
- However, Dr B stated that the IUCD was to be inserted only "in the event it was confirmed the ovaries were not implicated in the mass, and [if he] considered they should remain".
- I acknowledge that Dr Page considered the proposed IUCD insertion to constitute a severe departure from accepted standards; however, I also note his comments that the insertion of a Mirena IUCD would have been unlikely to cause harm. I have also considered Dr B's comment that the rationale for recommending the IUCD insertion was only in the event that the bilateral oophorectomy did not proceed, and the fact that Ms A never consented to the insertion, which subsequently did not occur. Accordingly, I do not consider that the proposed IUCD insertion constitutes a breach of the Code.

# Opinion: Clinic — no breach

I consider that the failures in this case relate solely to individual clinical error, and cannot be attributed to the systems in place at the clinic. Accordingly, I find that the clinic did not breach the Code.

#### Recommendation

I recommend that Dr B provide a written apology to Ms A. This should be sent to HDC, for forwarding to Ms A, within three weeks of the date of this report.

# Follow-up actions

- A copy of this report with details identifying the parties removed, except the independent advisor on this case, will be sent to the Medical Council of New Zealand and RANZCOG, and they will be advised of Dr B's name.
- A copy of this report with details identifying the parties removed, except the independent advisor on this case, will be sent to the Health Quality & Safety Commission and placed on the Health and Disability Commissioner website, <a href="https://www.hdc.org.nz">www.hdc.org.nz</a>, for educational purposes.

# Appendix A: Independent clinical advice to Commissioner

The following expert advice was obtained from obstetrician and gynaecologist Dr Ian Page:

"Complaint: [Ms A]/[Dr B]

Your ref: C19HDC01255

Thank you for your letter of 20 May 2020 and the enclosed documents, requesting expert advice to the Commissioner on the care provided by [Dr B] to [Ms A] during 2013. I have read and agree to follow the Commissioner's Guidelines for Independent Advisors.

I am a practising Obstetrician & Gynaecologist and have been a consultant for over 30 years. I obtained my MRCOG in 1985, my FRCOG in 1998 and my FRANZCOG in 2002. I have been employed for the past 20 years by Northland DHB. I have been a member of the RANZCOG Expert Witness register since 2012.

#### Background

[Dr B] first saw [Ms A] (then [in her forties]) on 25 September 2013. Her presenting symptoms were of bladder pressure, lower abdominal discomfort and left foot drop (related to previous deep vein thrombosis). MRI confirmed the presence of a large right pelvic mass. [Dr B] thought it was ovarian in origin, determined that it required removal and booked [Ms A] for surgery.

The surgery took place on 8 October 2013. [Dr B] performed a laparotomy and found two normal ovaries and a 15cm retro-peritoneal mass. He performed a bilateral oophorectomy and excised the mass.

No malignancy was identified in either of [Ms A's] ovaries. [Ms A] is concerned as to whether their removal was clinically indicated. She also claims not to have been adequately informed of the risks of the procedures and the consequences of losing her ovaries.

#### Advice Requested

You asked me to review the documents and advise whether the care provided to [Ms A] by [Dr B] was reasonable in the circumstances and why. You also asked me to comment specifically on:

- 1. Whether the removal of [Ms A's] ovaries was clinically indicated, and whether there were any other treatment options [Dr B] could reasonably have considered in the circumstances. You asked whether or not these should have been discussed with [Ms A] pre-operatively.
- 2. The adequacy of [Dr B's] clinical record keeping, particularly with regard to preoperative discussion of the long-term health effects associated with oophorectomy.

3. Whether there were any other matters in this case that warrant comment or amount to a departure from the standard of care/accepted practice.

#### Sources of Information

In assessing this case I have read:

- Referral from Nationwide Health and Disability Advocacy Service received 9 July 2019
- [Dr B's] responses to ACC dated 16 January 2014, 19 February 2015 and 2 August 2017
- Clinical records received from [the clinic]
- Clinical Records received from [medical centre]

#### Summary of the Case

[Dr B] first saw [Ms A] on Wednesday 25 September 2013. Her presenting symptoms were of bladder pressure, lower abdominal discomfort, heavy periods and left foot drop (related to previous deep vein thrombosis). An MRI on 10 September was reported as showing a large pedunculated right uterine/broad ligament leiomyoma with no evidence of overt malignancy. Despite this [Dr B] thought the mass was ovarian in origin and determined that it required removal.

He noted that he would review the MRI the following Tuesday (1 October), and booked [Ms A] for Hysteroscopy, D & C, Insertion of Mirena, Laparotomy and bilateral oophorectomy and omental biopsy. [Ms A] telephoned him on 2 October to say she did not wish to have the Mirena inserted.

His letter to [Ms A's] GP dated 25 September 2013 stated she had a 'large mass in the left pelvis which is undoubtedly ovarian' and that he would review the MRI with the radiologists prior to any surgery. He further noted 'she needed the mass removed, and it would be best to remove both ovaries and take an omental biopsy at the same time. The uterus can remain but it would help to insert a Mirena IUCD to reduce her heavy bleeding on anticoagulation.'

A pelvic ultrasound scan had previously been ordered by [Ms A's] GP and the report dated 3 September 2013 stated that both ovaries had been seen separate from the mass and were normal. The nature of the mass was difficult to ascertain and so an MRI was recommended. The MRI report from 10 September stated the mass was arising from the uterus. The GP noted she had a raised CA125 on 20 September 2013. In fact it was only marginally raised at 35.6, which is a level more consistent with a fibroid or endometriosis than an ovarian tumour.

The surgery took place on 8 October 2013. [Dr B] performed a hysteroscopy and D & C producing healthy curettings. He then performed a laparotomy and found a 15cm retroperitoneal mass in the right pelvis and two normal ovaries. He performed a bilateral salpingo-ophorectomy and excised the mass. He closed the abdomen in the usual way.

The nursing notes show that she was seen by [Dr B] the next morning, and further document she was seen by him prior to discharge on 11 October 2013. The histology report states that both tubes and ovaries were normal, as were the endometrial curettings and omental biopsy. The mass was reported as a leiomyoma (fibroid) with no evidence of malignancy.

A follow-up note from [Dr B] on 16 October 2013 recorded that (at follow-up that day) she was not having any flushes, that her bleeding had stopped and that no further follow-up was required.

#### My Assessment

You asked me to review the documents and advise whether the care provided to [Ms A] by [Dr B] was reasonable in the circumstances and why. You also asked me to comment specifically on:

1. Whether the removal of [Ms A's] ovaries was clinically indicated, and whether there were any other treatment options [Dr B] could reasonably have considered in the circumstances. You asked whether or not these should have been discussed with [Ms A] pre-operatively.

[Ms A's] ultrasound scan of 3 September 2013 showed both ovaries to be normal, with a pelvic mass that could be a fibroid or a haematoma, and recommended an MRI to try to clarify the lesion's origin and nature. The subsequent MRI (10 September 2013 ...) showed that the mass was what she believed was a large pedunculated right uterine/broad ligament leiomyoma (fibroid). [Dr B's] letter to the GP dated 25 September 2013 states that the mass is undoubtedly ovarian in origin, but that he would review the MRI before surgery occurred. There is nothing in the documents supplied to explain why [Dr B] felt the mass was ovarian, when the ultrasound and MRI were quite clear that both ovaries were normal and the mass was arising from the myometrium. There is also nothing to suggest that he did review the MRI with the radiologists.

I cannot understand why he proposed inserting a Mirena to control heavy periods when his intended operation (removing both ovaries) would mean that periods would cease. This is completely illogical, and a severe departure from an accepted standard of care. I think it would be viewed with mild disapproval by his peers, given that the insertion of the Mirena itself would be unlikely to cause any harm.

[Dr B's] operation states quite clearly that the ovaries appeared normal, and so removing them was not clinically indicated. His letter to ACC dated 19 February 2015 states the ovaries were removed to remove any potential source of malignant growth in the pelvis. If that was his intent then he should also have removed the uterus, to remove the potential for endometrial cancer developing within it. He had obtained [Ms A's] consent for the removal of her ovaries in the belief that the mass was ovarian. As noted above I cannot understand where that belief came from, given the MRI and ultrasound reports both said the ovaries had been identified and were normal.

As the scans suggested the mass was arising from the uterus, and not an ovary, [Dr B] should have discussed the options of:

- · simply removing the mass
- performing a total abdominal hysterectomy to remove the mass and the uterus from which it was arising (which would have dealt with the issue of [Ms A's] periods)
- performing a total abdominal hysterectomy and bilateral salpingo-oophorectomy to remove the mass, stop [Ms A] having further periods and reduce the risk of her developing ovarian cancer in the future.

All the options should have been discussed — there is no doubt that removing the mass was appropriate, and the issue is what else (if anything) needed to be removed with it. Most gynaecologists would have suggested that removing the whole uterus was appropriate, given that [Ms A] [who was aged in her forties] was unlikely to have wanted to have further children. I therefore believe that [Dr B] made a severe departure from the accepted standard of care in this case, which would be viewed with severe disapproval by his peers. He proposed the wrong operation, and even when he saw the ovaries were normal carried on with their removal.

2. The adequacy of [Dr B's] clinical record keeping, particularly with regard to preoperative discussion of the long-term health effects associated with oophorectomy.

In the absence of [Dr B's] notes and a response from him to the complaint it is not possible to give a comprehensive opinion on either part of this question.

[Dr B's] letter to ACC dated 2 August 2017 states he had no written record of what was said to [Ms A] about the consequences of the loss of her ovaries. He said there are usually no consequences from removing the ovaries at [Ms A's age]. He justified removing both ovaries as the 'uninvolved ovary would have some chance of containing the same pathology as the left ovary'.

Again I have no idea why he believed that [Ms A] had a mass in her left ovary, when the imaging had shown quite clearly that her ovaries were normal and that the mass on the right was a fibroid.

The apparent brevity of notes about the long-term effects of removing the ovaries is a mild departure from accepted standards, but would not be viewed with disapproval by many of his peers.

3. Whether there were any other matters in this case that warrant comment or amount to a departure from the standard of care/accepted practice.

In the absence of a response from [Dr B] I have had to draw critical conclusions that may be explicable. However on the surface it appears that [Dr B] formed an opinion about the pelvic mass and was not prepared to be diverted from it. He also proposed an illogical set of procedures, as noted above. This leads me to wonder if his judgment

was becoming adversely affected by something beyond his immediate control. I did not find anything else that warrants comment.

I do not have any personal or professional conflict of interest to declare with regard to this case. If you require any further comment or clarification please let me know.

Yours sincerely,

Dr Ian Page MB BS, FRCOG, FRANZCOG Consultant Obstetrician & Gynaecologist Whangarei Hospital"

#### **Further advice**

Dr Page was provided with a copy of the initial outpatient referral form and asked whether this changed his advice. In response, Dr Page advised:

"Thank you for the [public hospital] Referral form. There is nothing in it to warrant changing my opinion — in fact if anything it reinforces my comments."

Dr Page was provided with a copy of [Dr B's] statement to HDC, which included a response to Dr Page's advice report. Having considered [Dr B's] response, Dr Page confirmed that he did not wish to change his original advice report.

#### **Further advice**

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Dr Page provided the following additional advice regarding the long-term side effects of a bilateral oophorectomy:

"Thank you for your request for further clarification regarding the long term side effects when removing both the ovaries in someone of [Ms A's] age, and what [Dr B] should have discussed with [Ms A] having made the decision to undertake this procedure.

As you will have seen from the RANZCOG guidance<sup>1</sup> (I was one of the committee who wrote the advice) the evidence is conflicting. A large study suggested that ovarian removal was associated with an increased risk of all-cause mortality along with fatal and non-fatal coronary heart disease whilst another stated it was not associated with an increased risk of coronary heart disease, hip fracture or death. That is why the guidance states that there is no consensus about whether ovaries should be removed or retained (at hysterectomy for benign disease, and by implication without hysterectomy) and decisions should be made following patient consultation on an individualised basis.

However the RANZCOG guidance is quite clear that removal of the ovaries prior to the menopause is associated with more severe and prolonged vasomotor symptoms than those seen following natural menopause, and a reduction in libido and more sexual

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<sup>&</sup>lt;sup>1</sup> RANZCOG statement on "Managing the adnexae at the time of hysterectomy for benign gynaecological disease" (2009).

dysfunction. This should have been discussed with [Ms A], although the exact level of risk is hard to quantify. In addition for many women the risk does not actually become real, but that is only known with hindsight."

#### **Further advice**

Dr Page provided the following further advice on 20 April 2022:

"Thank you for your email of 31 March 2022 and the response from [Dr B] to the Deputy Commissioner's provisional opinion.

As you know I am a practising Obstetrician & Gynaecologist and have been a consultant for over 30 years. I obtained my MRCOG in 1985, my FRCOG in 1998 and my FRANZCOG in 2002. I have been employed for the past 22 years by Northland DHB. I have been a member of the RANZCOG Expert Witness register since 2012.

Although he has undoubtedly dealt with more cancer cases than I have, I am still able to offer an opinion on his care of [Ms A] as it was the care of a woman with a pelvic mass. I often take part in the gynaecology-oncology multi-disciplinary meetings for the Northern region which ensures I am also aware of sub-specialty practice in this area.

Where there is doubt about the accuracy of localisation from imaging my colleagues and I refer the case for review by the team. Where there is certainty in the imaging as to the location of a lesion such referral is not necessary. In a case like [Ms A's] I would have accepted the radiologist's assessment of the location of the mass and then planned to remove it, subject to the woman's informed consent. It should be noted that no imaging can exclude malignancy — that is a pathologist's decision once the specimen has been removed and examined in the laboratory.

[Dr B's] response refers to his notes of 25/9/13 recording a plan of Laparotomy/bilateral oophorectomy/omental biopsy/D&C. There is no mention of removing the mass, which he had previously said was undoubtedly ovarian in origin. Quite why (as a non-radiologist) he drew that conclusion remains unclear. So I remain of the opinion that he started the procedure believing he was going to find an ovarian mass.

His response talks about a hysterectomy being unnecessary and against the patient's request. However his justification for the removal of the ovaries was, in part, to avoid the need for re-operation. That is a reasonable thought, but in that case I would have planned a hysterectomy based on the radiological report stating the appearances are compatible with a large pedunculated right uterine/broad ligament leiomyoma. It would not be possible at surgery to determine where any malignancy within the mass would end, and as pedunculated means attached to the uterus I believe the proposed surgery should have included a hysterectomy.

As stated previously I do not have any personal or professional conflict of interest to declare with regard to this case. If you require any further comment or clarification please let me know."

#### **Further advice**

Dr Page provided the following further advice on 7 July 2022:

"Thank you for your email of 22 June 2022 and the response from [a lawyer] on [Dr B's] behalf to the Deputy Commissioner's provisional opinion.

I have re-read all the material I have been sent, including the original complaint from [Ms A].

I accept the rationale [Dr B] has given for the removal of [Ms A's] ovaries, but that rationale would then require (as I noted previously) the removal of the uterus in its entirety. The MRI report from 10 September 2013 states that the mass arises from the right posterolateral myometrium with a vascular pedicle of at least 3cm diameter at the level of the isthmus. It recorded the ovaries as being normal. As it is not possible to ascertain the limit of a sarcoma by visualisation alone removal of the uterus to which it was attached should have been undertaken. [Dr B] noted that in his response to [HDC] in March/April this year, where he notes the risk of incomplete removal. This is particularly the case given the potential difficulties with any further pelvic surgery for [Ms A] which [Dr B] correctly notes as the justification for removing her ovaries (see 17.9 in [the lawyer's] letter). [Dr B's] post-operative letter of 16 October 2013 to [Ms A's] GP states that the mass was a fibroid which had grown from the posterior aspect of the isthmus. This is consistent with his operation note stating there was a retroperitoneal mass in the right pelvis and polyp may have a vascular attachment to back of uterus. This contradicts statement 23 in [the lawyer's] letter.

When [Dr B] first saw [Ms A] he stated the mass was undoubtedly ovarian, and I would assume his discussion with [Ms A] went along those lines. That would then account for her complaint that her ovaries were removed in error.

His pre-operative discussion with [a colleague] immediately prior to the surgery on 8 October ([lawyer] 17.4) is said to have shown the retroperitoneal mass with a probability of sarcoma. Given the prior MRI showed a distinct pedicle from the uterus to the mass [Ms A] should have been informed of the change in diagnosis (from ovarian) and fully counselled about the need for hysterectomy to be undertaken. There is nothing in [Ms A's] notes or correspondence to show that she was advised to undergo hysterectomy, nor that she declined the advice. I note [Dr B's colleague's] statement, and his endorsement of the removal of [Ms A's] ovaries. However his recollection of the discussion was that the mass was possibly separate from the uterus and ovaries, whereas the MRI was quite clear that it was attached to the uterus.

I believe [Dr B's] proposal to insert a Mirena IUS remains illogical, as his notes of 14 July 2014 state 'avoid oestrogen because of previous DVTs'. He was aware of her DVT history from the outset.

As stated previously I do not have any personal or professional conflict of interest to declare with regard to this case. If you require any further comment or clarification please let me know."